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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/440,384
Filing Date: November 15, 1999
Appellant(s): KINGSFORD, HOWARD A.

MAILED

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GROUP 1700

James W. Babineau
For Appellant

SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to the appeal brief filed August 15, 2005 appealing from the Office action mailed September 30, 2004.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal, and Applicant has stated that there are none.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 10, 16 – 17, 19 – 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Reed et al (U.S. Patent No. 5,312,456).

With regard to Claim 19, Reed et al. disclose an array (plurality; column 3, lines 7 - 9) of surfaces having a pointed shape (therefore a tip; column 3, lines 14 - 17) which is used to pierce and therefore penetrate, skin (column 4, lines 28 - 32) formed of plastic (column 3, lines 40 - 42); the skin attachment member is therefore a skin attachment member of plastic resin, and is configured to penetrate into the epidermal skin layer; the skin attachment has a sheet form backing from which the penetrating elements extend integrally (base; column 7, lines 26 - 27), and is used as a bandage (column 5, lines 21 - 26); the skin penetrating elements include a retention barb extending from an outer surface of the skin penetrating element (a barb which bonds with skin; column 4, lines 28 - 34); the skin penetrating elements are integral with the backing, and are therefore formed integrally (column 3, lines 32 - 34); the plastic comprises a single plastic resin (polysulphone; column 3, lines 44 - 45).

With regard to Claim 4, the surfaces of the skin penetrating elements have pointed shapes (column 3, lines 16 - 22; column 60 - 66), and therefore, pointed tips.

With regard to Claim 10, each skin penetrating element includes two barbs (column 3, lines 60 - 66, Figure 6).

With regard to Claim 16, the scope of the claim falls within the limitation of Reed et al. as discussed above.

With regard to Claim 17, the skin penetrating elements have pointed shapes, and therefore define depressions on the surface.

With regard to Claim 20, as stated previously, the penetrating element has a pointed shape; it therefore tapers continuously from the base to the tip.

With regard to Claim 21, Reed et al disclose barbs having a length ranging from 4 - 18 μ m high (column 6, lines 11 - 28); the claimed aspect of the skin penetrating elements being disposed at different distances from the backing therefore reads on Reed et al.

With regard to Claim 23, as stated previously, the barb extends from the outer surface of the penetrating element; it therefore has a lower surface disposed substantially perpendicular to a central axis of the skin penetrating element from which it extends.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 - 3, 5 - 9, 11 - 12, 18, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al (U.S. Patent No. 5,312,456).

With regard to Claims 2 – 3 and 22, Reed et al. fail to disclose a skin penetrating element comprising a cone - shaped body having a diameter of about 0.003." However, Reed et al disclose a pointed solid triangular body having a width of 4 - 18 μm (column 6, lines 11 - 28). It would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a skin penetrating element comprising a cone - shaped body having a diameter of about 0.003," since the modification would have involved a mere change in shape. A change in shape is generally recognized as being within the level of ordinary skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966.).

With regard to Claims 5 - 9, 11 - 12 and 18, Reed et al. fail to disclose a skin penetrating element having a diameter of 0.003" and a skin penetrating element having a length of 0.012" and a backing having a thickness of 0.003 to 0.008", and a retention barb which is 0.008" to 0.0095" from the backing, and a retention barb with a length of 0.00015', and a retention barb which tapers from a thickness of 0.0001" to a point at an angle of 72 degrees, and a skin attachment member having a density of 400 skin penetrating elements in a 0.1 in² area and elements are spaced apart from each other a distance of 0.003 inches, and the elements perpendicular to the backing. However, Reed et al disclose a skin penetrating element having a diameter of greater than 0.1 μm (column 6, lines 61 - 65), and a skin penetrating element having a length of 4 – 18 μm long (therefore 4 - 18 μm from the backing; column 6, lines 11 - 28) and a backing having a thickness of at least a fraction of 1 μm (the element comprises a backing; column 3, lines 32 - 34), and a retention barb with a length of 12 μm , and a retention barb which tapers from a thickness of 0.1 μm to a point at an angle of at least 1 degree from the thickness to a pointed piercing barb, and a skin attachment member having a density of 200,000 skin

Art Unit: 1772

penetrating elements in a 1 cm^2 area (column 6, lines 61 - 65) and the elements are spaced apart from each other a distance of at $4 - 18\text{ }\mu\text{m}$ (column 6, lines 11 - 28) and teaches that maximum flexibility is desired (column 4, lines 47 - 48). Therefore, one of ordinary skill in the art would recognize the advantage of varying the diameter, length and angle of point of the penetrating element, the thickness of the backing and the number of elements per area to obtain a desired range of flexibility. Therefore, the flexibility would be readily determined through routine optimization of diameter, length and angle of point of the penetrating element, the thickness of the backing and the number of elements per area by one having ordinary skill in the art depending on the desired end use of the product.

It therefore would be obvious for one of ordinary skill in the art to vary the diameter, length and angle of point of the penetrating element, the thickness of the backing and the number of elements per area in order to obtain a desired flexibility, since the flexibility would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Reed et al, in the absence of unexpected results. It therefore would be obvious for one of ordinary skill in the art to vary the diameter, length and angle of point of the penetrating element, the thickness of the backing and the number of elements per area, since the diameter, length and angle of point of the penetrating element, the thickness of the backing and the number of elements per area would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Reed et al.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456) in view of Fye (U.S. Patent No. 5,031,609).

Reed et al disclose a skin - attachment member as discussed above. With regard to Claim 13, Reed et al. fail to disclose a skin attachment member comprising nylon. Fye teaches the use of nylon in the making of bandages, for the purpose of making bandages which are light - weight and hand - washable (column 2, lines 34 - 39). Since Reed et al and Fye, both teach fastening to skin (column 5, lines 21 - 26 of Reed et al; column 2, lines 34 - 39 of Fye) one of ordinary skill in the art would have recognized the advantage of providing for the nylon of Fye in the skin attachment member of Reed et al, depending on the desired weight and hand - washability of the end product as taught by Reed et al.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for nylon in Reed et al. in order to obtain bandages which are light - weight and hand - washable as taught by Fye.

Claims 14 - 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al. (U.S. Patent No. 5,312,456) in view of Coates (U.S. Patent No. 4,219,019).

Reed et al disclose a skin - attachment member as discussed above. With regard to Claims 14 and 15, Reed et al. fail to disclose a skin attachment member comprising polyethylene terephthalate. Coates teaches that polyethylene terephthalate is notoriously well known in the art in the making of bandages (column 5, lines 14 - 19), since polyethylene terephthalate possesses bulk and conformability in the bandage art (column 1, lines 60 - 63). Therefore, one of ordinary skill in the art would have recognized the advantage of providing for the polyethylene

terephthalate of Coates in Reed et al, which is a bandage, depending on the desired bulk and conformability of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for polyethylene terephthalate in Reed et al. in order to obtain bandages which possesses bulk and conformability as taught by Coates.

(8) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Evidence Relied Upon

5,312,456	Reed et al	5-1994
5,031,609	Fye	7-1991
4,219,019	Coates	8-1980

(10) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

(11) Response to Argument

Appellant argues that Reed et al does not enable one of ordinary skill in the art to make skin penetrating elements as recited in the claimed invention, because the only method of making

that Reed et al discloses is a photochemical etching process in which layers of different materials are sequentially etched to leave barbs of the desired shape.

However, Reed et al discloses photochemical etching as 'a method of making' (column 5, line 39), and therefore discloses that the invention is not limited to photochemical etching as the only method of making. Furthermore, Reed et al is not required to state all possible methods of making the invention for the disclosure to be enabling.

Appellant also argues that the phrase 'formed integrally of a single plastic resin' should not be read as a process limitation; the limitation, Appellant argues, should be read as a structural limitation and given full patentable weight.

However, the phrase 'formed integrally of a single plastic resin' has been read as a structural limitation and has been given full patentable weight; the penetrating elements disclosed by Reed et al comprise a single plastic resin (polysulphone; column 3, lines 44 – 45) and the skin penetrating elements comprise components which are integral with each other (column 3, lines 32 – 34) and are therefore formed integrally.

Appellant also argues that in declaration under 37 C.F.R. 1.132, it has been stated that Reed et al discloses etching, specifically undercut etching and lateral undercutting, as a method of making, but that Reed does not disclose a barb that is formed integrally of a single plastic resin.

However, as stated above, the skin penetrating elements disclosed by Reed et al comprise components which are integral with each other, and are therefore formed integrally.

Appellant also argues that the remarks in the declaration have not been commented on or considered, and have been dismissed out of hand.

However, the remarks in the declaration were considered in the Office Action of January 2, 2003, and therefore were not dismissed.

Appellant also argues that although Reed et al disclose that the base, head and support are made of a single plastic resin, one of ordinary skill in the art would not understand Reed et al to have disclosed skin penetrating elements formed integrally of a single plastic resin; a fair reading of Reed et al, Appellant argues, requires the head to be formed of a first material and the body to be formed of a different material.

However, Reed et al discloses a base, head and support made of a rigid material comprising polysulphone (column 3, lines 40 – 44) and therefore made of a single plastic resin.

Appellant also argues that the significance of the recited shape with respect to skin penetration and retention, as well as limiting the detrimental effect to the skin due to penetration, have been explained.

However, it is unclear why the difference in shape between the claimed invention and the prior art of record would not be within the level of one of ordinary skill in the art.

Appellant also argues that Reed et al does not disclose that the diameter, length and angle of point, thickness of backing and number of elements would be determined by optimization or are related to flexibility.

However, as stated above, Reed et al teach the desirability of maximum flexibility, and therefore disclose the selection of the physical parameters of the skin attachment member to achieve the flexibility.

Appellant also argues that none of the secondary references provides insight into how one could have produced a skin attachment member of the structure claimed.

However, as stated above, Reed et al, is not required to state all possible methods of making the invention for the disclosure to be enabling; furthermore, as stated above, the physical structure which is claimed is disclosed by Reed et al.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,
Marc A. Patterson
Marc A. Patterson, PhD.

June 5, 2006

Conferees

Carol Chaney *Carol Chaney*

Harold Pyon *Harold Pyon*